

AMENDED IN ASSEMBLY AUGUST 8, 2006

AMENDED IN ASSEMBLY AUGUST 7, 2006

AMENDED IN ASSEMBLY JUNE 15, 2006

AMENDED IN SENATE MAY 24, 2006

AMENDED IN SENATE MAY 2, 2006

AMENDED IN SENATE APRIL 18, 2006

AMENDED IN SENATE MARCH 29, 2006

## SENATE BILL

**No. 1555**

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**Introduced by Senator Speier**

**(Coauthors: Senators Bowen and Kuehl)**

(Coauthors: Assembly Members Jones, Koretz, Mullin, and Pavley)

February 23, 2006

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An act to amend Sections 124977 and ~~125001~~ 125055 of, to add Sections 1604.6 and 125002 to, and to add Article 4 (commencing with Section 123370) to Chapter 1 of Part 2 of Division 106 of, the Health and Safety Code, relating to *prenatal testing and* cord blood banking, and making an appropriation therefor.

### LEGISLATIVE COUNSEL'S DIGEST

SB 1555, as amended, Speier. Umbilical cord blood banking: ~~education~~; *education; prenatal screening*.

(1) Existing law imposes various responsibilities upon the State Department of Health Services and prenatal care providers with respect to prenatal care, screening, and counseling.

*This bill would require the department to conduct the Umbilical Blood Community Awareness Campaign, which would require the*

*department to, among other things, provide awareness, assistance, and information regarding umbilical cord blood banking options, as specified. This bill would authorize a primary prenatal care provider, as defined, to provide to a woman who is known to be pregnant, during the first prenatal visit, information developed by the department pursuant to this bill regarding her options with respect to umbilical cord blood banking.*

This bill would require the department to ~~develop standardized, objective~~ also provide this information, available in Cantonese, English, Spanish, and Vietnamese, about cord blood donation as specified. The bill would require that the information be made available on the Internet Web sites of the licensing boards or agencies that oversee primary prenatal care providers. The bill would specify that those provisions requiring the department to develop that information only be implemented, upon a determination by the Director of Finance, that sufficient private donations have been collected and deposited into the Umbilical Cord Blood Education Account, which the bill would create and continuously appropriate for this purpose.

**Existing**

(2) Existing law, administered by the State Department of Health Services, contains provisions governing the licensure of blood banks. A violation of these provisions is a misdemeanor.

This bill would, notwithstanding any other provision of law, provide that a *licensed* blood bank, ~~in order to be licensed~~ *may receive a special license from the department* to provide cord blood banking storage services, ~~shall be required to be only if it is~~ accredited by the American Association of Blood Banks.

Because a violation of this provision would create a new crime, this bill would impose a state-mandated local program.

(2)

(3) Existing law, the Hereditary Disorders Act, declares the intent of the Legislature that the state's hereditary disorders program activities are to be fully supported by fees collected for services provided by the program, unless otherwise provided. Existing law requires the State Department of Health Services to charge a fee to all payers for any tests or activities performed pursuant to provisions relating to genetic disorder prevention services, including the Hereditary Disorders Act. Existing law requires that any fee charged for screening and followup services provided to Medi-Cal eligible

persons, health care service plan enrollees, or persons covered by disability insurance policies are to be paid directly to the Genetic Disease Testing Fund, a continuously appropriated fund, to be used for the purposes of the Hereditary Disorders Act.

This bill would authorize the expenditure of funds from the Genetic Disease Testing Fund for the expansion of the Genetic Disease Branch Screening Information System *to include the expansion of prenatal screenings* through the amendment of the Genetic Branch Screening Information Systems contracts, and would exempt that expansion from specified requirements governing public contracts and contracts for information technology projects. By expanding the purposes for which moneys from the fund may be expended, the bill would make an appropriation.

~~Existing law requires the department to establish a program for the development, provision, and evaluation of genetic disease testing, and requires the department to expand statewide screening of newborns to include tandem mass spectrometry screening for various conditions and disorders. Existing law also requires the department to report to the Legislature regarding the progress of the program on or before July 1, 2006.~~

~~This bill would require the department to expand prenatal screening to include inhibin and first trimester screening.~~

*(4) Existing law requires the department to administer a statewide program for prenatal testing for genetic disorders and birth defects, including, but not limited to, ultrasound, amniocentesis, chorionic villus sampling, and blood testing for genetic disorders and birth defects.*

*This bill would require the department to expand prenatal screening to include all tests that meet or exceed the current standard of care as recommended by nationally recognized medical or genetic organizations, including, but not limited to, inhibin, would authorize the department to charge a prescribed fee for this testing and would require the department, not later than July 1, 2007, to report to the Legislature on the progress of this expansion, including an estimate of the costs for screening, followup, and treatment as compared to costs and morbidity averted by this testing under the program. Because these fees are deposited in the continuously appropriated Genetic Disease Testing Fund, the bill would constitute an appropriation.*

~~Existing~~

(5) *Existing* law, the Birth Defects Monitoring Program, requires the Director of Health Services to maintain a system for the collection of prescribed information on birth defects. This bill would make the Birth Defects Monitoring Program part of the department's maternal, child and adolescent health program. This bill would also provide for an increase in prenatal screening fees to support a variety of Birth Defects Monitoring Program activities and specify the steps for release of pregnancy blood samples for research purposes. Because these fees are deposited in the continuously appropriated Genetic Disease Testing Fund, the bill would constitute an appropriation.

(3)

(6) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: yes. Fiscal committee: yes.  
State-mandated local program: yes.

*The people of the State of California do enact as follows:*

1 SECTION 1. Section 1604.6 is added to the Health and  
2 Safety Code, to read:

3 1604.6. Notwithstanding any other provision of law, a blood  
4 bank, ~~in order to be licensed~~ *licensed pursuant to this chapter,*  
5 *may receive a special license from the department to provide*  
6 *umbilical cord blood banking storage services, shall be required*  
7 ~~to be only if it is~~ *accredited by the American Association of*  
8 *Blood Banks.*

9 SEC. 2. Article 4 (commencing with Section 123370) is  
10 added to Chapter 1 of Part 2 of Division 106 of the Health and  
11 Safety Code, to read:

12  
13 Article 4. Cord Blood Banking Education  
14

15 123370. *The department shall conduct the Umbilical Blood*  
16 *Community Awareness Campaign to do all of the following:*

17 (a) *Provide awareness, assistance, and information regarding*  
18 *umbilical cord blood banking options using brochures,*

1 *television, print media, radio, Internet Web sites, outdoor*  
2 *advertising, and other media, where appropriate to disseminate*  
3 *information to licensed prenatal care providers, Family PACT*  
4 *providers, and pregnant women.*

5 *(b) Establish an Internet Web site to provide information*  
6 *about umbilical cord blood banking options that is accessible to*  
7 *prenatal care providers, pregnant women, and the general*  
8 *public.*

9 *(c) Undertake public education activities related to umbilical*  
10 *cord blood donation to targeted populations, as appropriate.*

11 ~~123370.~~

12 122371. (a) The State Department of Health Services shall  
13 develop standardized, objective information about *umbilical* cord  
14 blood donation that is sufficient to allow a pregnant woman to  
15 make an informed decision on whether to participate in a private  
16 or public umbilical cord blood banking program. This  
17 information shall include, but not be limited to, all of the  
18 following:

19 (1) The current and potential future medical uses of stored  
20 umbilical cord blood.

21 (2) The benefits and risks involved in umbilical cord blood  
22 banking.

23 (3) The medical process involved in umbilical cord blood  
24 banking.

25 (4) Medical or family history criteria that can impact a  
26 family's consideration of umbilical cord banking.

27 (5) An explanation of the differences between public and  
28 private umbilical cord blood banking.

29 (6) The availability and costs of public or private umbilical  
30 cord blood banks.

31 (7) Medical or family history criteria that can impact a  
32 family's consideration of umbilical cord blood banking.

33 (8) An explanation that the practices and policies of blood  
34 banks may vary with respect to accreditation, cord blood  
35 processing and storage methods, costs, and donor privacy.

36 (b) The information provided by the department pursuant to  
37 subdivision (a) shall be made available in Cantonese, English,  
38 Spanish, and Vietnamese.

39 (c) The information provided by the department pursuant to  
40 subdivision (a) shall be made available on the Internet Web sites

1 of the licensing boards that have oversight over primary prenatal  
2 care providers.

3 (d) (1) *The primary prenatal care provider of a woman who is*  
4 *known to be pregnant may, during the first prenatal visit, provide*  
5 *her with information developed by the department regarding her*  
6 *options with respect to umbilical cord blood banking at the same*  
7 *time the provider provides information regarding the use and*  
8 *availability of prenatal screening for birth defects of the fetus, as*  
9 *required by Section 6527 of Title 17 of the California Code of*  
10 *Regulations.*

11 (2) *For purposes of this section, a “prenatal care provider”*  
12 *means a health care provider licensed pursuant to Division 2*  
13 *(commencing with Section 500) of the Business and Professions*  
14 *Code, or pursuant to an initiative act referred to in that division,*  
15 *who provides prenatal medical care within his or her scope of*  
16 *practice.*

17 (d)

18 (e) The department shall only implement this section upon a  
19 determination by the Director of Finance, that sufficient private  
20 donations have been collected and deposited into the Umbilical  
21 Cord Blood Education Account, which is hereby created in the  
22 State Treasury and which, notwithstanding Section 13340 of the  
23 Government Code, is hereby continuously appropriated for  
24 purposes of this section. No public funds shall be used to  
25 implement this section. If sufficient funds are collected and  
26 deposited into the account, the Director of Finance shall file a  
27 written notice thereof with the Secretary of State.

28 SEC. 3. ~~Section 124977 of the Health and Safety Code is~~  
29 ~~amended to read:~~

30 ~~124977. (a) It is the intent of the Legislature that, unless~~  
31 ~~otherwise specified, the program carried out pursuant to this~~  
32 ~~chapter be fully supported from fees collected for services~~  
33 ~~provided by the program.~~

34 ~~(b) (1) The department shall charge a fee to all payers for any~~  
35 ~~tests or activities performed pursuant to this chapter. The amount~~  
36 ~~of the fee shall be established by regulation and periodically~~  
37 ~~adjusted by the director in order to meet the costs of this chapter.~~  
38 ~~Notwithstanding any other provision of law, any fees charged for~~  
39 ~~prenatal screening and followup services provided to persons~~  
40 ~~enrolled in the Medi-Cal program, health care service plan~~

1 enrollees, or persons covered by health insurance policies, shall  
2 be paid in full directly to the Genetic Disease Testing Fund,  
3 subject to all terms and conditions of each enrollee's or insured's  
4 health care service plan or insurance coverage, whichever is  
5 applicable, including, but not limited to, copayments and  
6 deductibles applicable to these services, and only if these  
7 copayments, deductibles, or limitations are disclosed to the  
8 subscriber or enrollee pursuant to the disclosure provisions of  
9 Section 1363.

10 (2) The department shall expeditiously undertake all steps  
11 necessary to implement the fee collection process, including  
12 personnel, contracts, and data processing, so as to initiate the fee  
13 collection process at the earliest opportunity.

14 (3) The director shall convene, in the most cost-efficient  
15 manner and using existing resources, a working group comprised  
16 of health insurance, health care service plan, hospital, consumer,  
17 and department representatives to evaluate newborn and prenatal  
18 screening fee billing procedures, and recommend to the  
19 department ways to improve these procedures in order to  
20 improve efficiencies and enhance revenue collections for the  
21 department and hospitals. In performing its duties, the working  
22 group may consider models in other states. The working group  
23 shall make its recommendations by March 1, 2005.

24 (4) Effective for services provided on and after July 1, 2002,  
25 the department shall charge a fee to the hospital of birth, or, for  
26 births not occurring in a hospital, to families of the newborn, for  
27 newborn screening and followup services. The hospital of birth  
28 and families of newborns born outside the hospital shall make  
29 payment in full to the Genetic Disease Testing Fund. The  
30 department shall not charge or bill Medi-Cal beneficiaries for  
31 services provided under this chapter.

32 (5) The department shall charge a fee for prenatal screening to  
33 support the pregnancy blood sample storage, testing, and  
34 research activities of the Birth Defects Monitoring Program.

35 (6) The initial prenatal screening fee increase for activities of  
36 the Birth Defects Monitoring Program shall be ten dollars (\$10).

37 (7) The only funds from the Genetic Disease Testing Fund that  
38 may be used for the purpose of supporting the pregnancy blood  
39 sample storage, testing, and research activities of the Birth  
40 Defects Monitoring Program are those prenatal screening fees

1 assessed and collected specifically to support those Birth Defects  
2 Monitoring activities:

3 (e) (1) ~~The Legislature finds that timely implementation of~~  
4 ~~changes in genetic screening programs and continuous~~  
5 ~~maintenance of quality statewide services requires expeditious~~  
6 ~~regulatory and administrative procedures to obtain the most~~  
7 ~~cost-effective electronic data processing, hardware, software~~  
8 ~~services, testing equipment, and testing and followup services:~~

9 (2) ~~The expenditure of funds from the Genetic Disease Testing~~  
10 ~~Fund for these purposes shall not be subject to Section 12102 of,~~  
11 ~~and Chapter 2 (commencing with Section 10290) of Part 2 of~~  
12 ~~Division 2 of, the Public Contract Code, or to Division 25.2~~  
13 ~~(commencing with Section 38070). The department shall provide~~  
14 ~~the Department of Finance with documentation that equipment~~  
15 ~~and services have been obtained at the lowest cost consistent~~  
16 ~~with technical requirements for a comprehensive high-quality~~  
17 ~~program:~~

18 (3) ~~The expenditure of funds from the Genetic Disease Testing~~  
19 ~~Fund for implementation of the Tandem Mass Spectrometry~~  
20 ~~screening for fatty acid oxidation, amino acid, and organic acid~~  
21 ~~disorders, and screening for congenital adrenal hyperplasia may~~  
22 ~~be implemented through the amendment of the Genetic Disease~~  
23 ~~Branch Screening Information System contracts and shall not be~~  
24 ~~subject to Chapter 3 (commencing with Section 12100) of Part 2~~  
25 ~~of Division 2 of the Public Contract Code, Article 4~~  
26 ~~(commencing with Section 19130) of Chapter 5 of Part 2 of~~  
27 ~~Division 5 of Title 2 of the Government Code, and any policies,~~  
28 ~~procedures, regulations or manuals authorized by those laws:~~

29 (4) ~~The expenditure of funds from the Genetic Disease Testing~~  
30 ~~Fund may be made for any purpose related to the Genetic~~  
31 ~~Disease Branch Screening Information System. Genetic Disease~~  
32 ~~Branch Screening Information System enhancements may be~~  
33 ~~implemented through the amendment of the existing Genetic~~  
34 ~~Disease Branch Screening Information System contracts, and~~  
35 ~~shall not be subject to Chapter 2 (commencing with Section~~  
36 ~~12100) of Part 2 of Division 2 of the Public Contract Code,~~  
37 ~~Article 4 (commencing with Section 19130) of Chapter 5 of Part~~  
38 ~~2 of Division 5 of Title 2 of the Government Code, and State~~  
39 ~~Administrative Manual Sections 4800 to 5180, inclusive, as they~~  
40 ~~relate to the approval of information technology projects, or~~



1 approval of increases in the duration or costs of information  
2 technology projects. These provisions shall apply to the design,  
3 development and implementation of the expansion and to the  
4 maintenance and operation of the Genetic Disease Branch  
5 Screening Information System, including change requests, once  
6 the expansion is implemented.

7 (d) (1) The department may adopt emergency regulations to  
8 implement and make specific this chapter in accordance with  
9 Chapter 3.5 (commencing with Section 11340) of Part 1 of  
10 Division 3 of Title 2 of the Government Code. For the purposes  
11 of the Administrative Procedure Act, the adoption of regulations  
12 shall be deemed an emergency and necessary for the immediate  
13 preservation of the public peace, health and safety, or general  
14 welfare. Notwithstanding Chapter 3.5 (commencing with Section  
15 11340) of Part 1 of Division 3 of Title 2 of the Government  
16 Code, these emergency regulations shall not be subject to the  
17 review and approval of the Office of Administrative Law.  
18 Notwithstanding Section 11346.1 and Section 11349.6 of the  
19 Government Code, the department shall submit these regulations  
20 directly to the Secretary of State for filing. The regulations shall  
21 become effective immediately upon filing by the Secretary of  
22 State. Regulations shall be subject to public hearing within 120  
23 days of filing with the Secretary of State and shall comply with  
24 Sections 11346.8 and 11346.9 of the Government Code or shall  
25 be repealed.

26 (2) The Office of Administrative Law shall provide for the  
27 printing and publication of these regulations in the California  
28 Code of Regulations. Notwithstanding Chapter 3.5 (commencing  
29 with Section 11340) of Part 1 of Division 3 of Title 2 of the  
30 Government Code, the regulations adopted pursuant to this  
31 chapter shall not be repealed by the Office of Administrative  
32 Law and shall remain in effect until revised or repealed by the  
33 department.

34 (3) The Legislature finds and declares that the health and  
35 safety of California newborns is in part dependent on an effective  
36 and adequately staffed genetic disease program, the cost of which  
37 shall be supported by the fees generated by the program.

38 *SEC. 3. Section 124977 of the Health and Safety Code is*  
39 *amended to read:*

1 124977. (a) It is the intent of the Legislature that, unless  
2 otherwise specified, the program carried out pursuant to this  
3 chapter be fully supported from fees collected for services  
4 provided by the program.

5 (b) (1) The department shall charge a fee to all payers for any  
6 tests or activities performed pursuant to this chapter. The amount  
7 of the fee shall be established by regulation and periodically  
8 adjusted by the director in order to meet the costs of this chapter.  
9 Notwithstanding any other provision of law, any fees charged for  
10 prenatal screening and followup services provided to persons  
11 enrolled in the Medi-Cal program, health care service plan  
12 enrollees, or persons covered by health insurance policies, shall  
13 be paid in full directly to the Genetic Disease Testing Fund,  
14 subject to all terms and conditions of each enrollee's or insured's  
15 health care service plan or insurance coverage, whichever is  
16 applicable, including, but not limited to, copayments and  
17 deductibles applicable to these services, and only if these  
18 copayments, deductibles, or limitations are disclosed to the  
19 subscriber or enrollee pursuant to the disclosure provisions of  
20 Section 1363.

21 (2) The department shall expeditiously undertake all steps  
22 necessary to implement the fee collection process, including  
23 personnel, contracts, and data processing, so as to initiate the fee  
24 collection process at the earliest opportunity.

25 (3) The director shall convene, in the most cost-efficient  
26 manner and using existing resources, a working group comprised  
27 of health insurance, health care service plan, hospital, consumer,  
28 and department representatives to evaluate newborn and prenatal  
29 screening fee billing procedures, and recommend to the  
30 department ways to improve these procedures in order to  
31 improve efficiencies and enhance revenue collections for the  
32 department and hospitals. In performing its duties, the working  
33 group may consider models in other states. The working group  
34 shall make its recommendations by March 1, 2005.

35 (4) Effective for services provided on and after July 1, 2002,  
36 the department shall charge a fee to the hospital of birth, or, for  
37 births not occurring in a hospital, to families of the newborn, for  
38 newborn screening and followup services. The hospital of birth  
39 and families of newborns born outside the hospital shall make  
40 payment in full to the Genetic Disease Testing Fund. The

1 department shall not charge or bill Medi-Cal beneficiaries for  
2 services provided under this chapter.

3 (5) *The department shall charge a fee for prenatal screening*  
4 *to support the pregnancy blood sample storage, testing, and*  
5 *research activities of the Birth Defects Monitoring Program.*

6 (6) *The initial prenatal screening fee increase for activities of*  
7 *the Birth Defects Monitoring Program shall be ten dollars (\$10).*

8 (7) *The only funds from the Genetic Disease Testing Fund that*  
9 *may be used for the purpose of supporting the pregnancy blood*  
10 *sample storage, testing, and research activities of the Birth*  
11 *Defects Monitoring Program are those prenatal screening fees*  
12 *assessed and collected specifically to support those Birth Defects*  
13 *Monitoring Program activities.*

14 (c) (1) The Legislature finds that timely implementation of  
15 changes in genetic screening programs and continuous  
16 maintenance of quality statewide services requires expeditious  
17 regulatory and administrative procedures to obtain the most  
18 cost-effective electronic data processing, hardware, software  
19 services, testing equipment, and testing and followup services.

20 (2) The expenditure of funds from the Genetic Disease Testing  
21 Fund for these purposes shall not be subject to Section 12102 of,  
22 and Chapter 2 (commencing with Section 10290) of Part 2 of  
23 Division 2 of, the Public Contract Code, or to Division 25.2  
24 (commencing with Section 38070). The department shall provide  
25 the Department of Finance with documentation that equipment  
26 and services have been obtained at the lowest cost consistent  
27 with technical requirements for a comprehensive high-quality  
28 program.

29 (3) The expenditure of funds from the Genetic Disease Testing  
30 Fund for implementation of the Tandem Mass Spectrometry  
31 screening for fatty acid oxidation, amino acid, and organic acid  
32 disorders, and screening for congenital adrenal hyperplasia may  
33 be implemented through the amendment of the Genetic Disease  
34 Branch Screening Information System contracts and shall not be  
35 subject to Chapter 3 (commencing with Section 12100) of Part 2  
36 of Division 2 of the Public Contract Code, Article 4  
37 (commencing with Section 19130) of Chapter 5 of Part 2 of  
38 Division 5 of Title 2 of the Government Code, and any policies,  
39 procedures, regulations or manuals authorized by those laws.

1 (4) The expenditure of funds from the Genetic Disease Testing  
2 Fund for the expansion of the Genetic Disease Branch Screening  
3 Information System to include cystic fibrosis and biotinidase  
4 may be implemented through the amendment of the Genetic  
5 Disease Branch Screening Information System contracts, and  
6 shall not be subject to Chapter 2 (commencing with Section  
7 10290) or Chapter 3 (commencing with Section 12100) of Part 2  
8 of Division 2 of the Public Contract Code, Article 4  
9 (commencing with Section 19130) of Chapter 5 of Part 2 of  
10 Division 5 of Title 2 of the Government Code, or Sections 4800  
11 to 5180, inclusive, of the State Administrative Manual as they  
12 relate to approval of information technology projects or approval  
13 of increases in the duration or costs of information technology  
14 projects. This paragraph shall apply to the design, development,  
15 and implementation of the expansion, and to the maintenance and  
16 operation of the Genetic Disease Branch Screening Information  
17 System, including change requests, once the expansion is  
18 implemented.

19 (d) (1) The department may adopt emergency regulations to  
20 implement and make specific this chapter in accordance with  
21 Chapter 3.5 (commencing with Section 11340) of Part 1 of  
22 Division 3 of Title 2 of the Government Code. For the purposes  
23 of the Administrative Procedure Act, the adoption of regulations  
24 shall be deemed an emergency and necessary for the immediate  
25 preservation of the public peace, health and safety, or general  
26 welfare. Notwithstanding Chapter 3.5 (commencing with Section  
27 11340) of Part 1 of Division 3 of Title 2 of the Government  
28 Code, these emergency regulations shall not be subject to the  
29 review and approval of the Office of Administrative Law.  
30 Notwithstanding Section 11346.1 and Section 11349.6 of the  
31 Government Code, the department shall submit these regulations  
32 directly to the Secretary of State for filing. The regulations shall  
33 become effective immediately upon filing by the Secretary of  
34 State. Regulations shall be subject to public hearing within 120  
35 days of filing with the Secretary of State and shall comply with  
36 Sections 11346.8 and 11346.9 of the Government Code or shall  
37 be repealed.

38 (2) The Office of Administrative Law shall provide for the  
39 printing and publication of these regulations in the California  
40 Code of Regulations. Notwithstanding Chapter 3.5 (commencing

1 with Section 11340) of Part 1 of Division 3 of Title 2 of the  
2 Government Code, the regulations adopted pursuant to this  
3 chapter shall not be repealed by the Office of Administrative  
4 Law and shall remain in effect until revised or repealed by the  
5 department.

6 (3) The Legislature finds and declares that the health and  
7 safety of California newborns is in part dependent on an effective  
8 and adequately staffed genetic disease program, the cost of which  
9 shall be supported by the fees generated by the program.

10 SEC. 4. ~~Section 125001 of the Health and Safety Code is~~  
11 ~~amended to read:~~

12 ~~125001. (a) The department shall establish a program for the~~  
13 ~~development, provision, and evaluation of genetic disease~~  
14 ~~testing, and may provide laboratory testing facilities or make~~  
15 ~~grants to, contract with, or make payments to, any laboratory that~~  
16 ~~it deems qualified and cost effective to conduct testing or with~~  
17 ~~any metabolic specialty clinic to provide necessary treatment~~  
18 ~~with qualified specialists. The program shall provide genetic~~  
19 ~~screening and followup services for persons who have the~~  
20 ~~screening.~~

21 ~~(b) (1) The department shall expand statewide screening of~~  
22 ~~newborns to include tandem mass spectrometry screening for~~  
23 ~~fatty acid oxidation, amino acid, and organic acid disorders and~~  
24 ~~congenital adrenal hyperplasia as soon as possible. The~~  
25 ~~department shall also expand prenatal screening to include~~  
26 ~~inhibin and first trimester screening. The department shall~~  
27 ~~provide information with respect to these disorders and available~~  
28 ~~testing resources to all women receiving prenatal care and to all~~  
29 ~~women admitted to a hospital for delivery. If the department is~~  
30 ~~unable to provide this statewide screening by August 1, 2005, the~~  
31 ~~department shall temporarily obtain these testing services~~  
32 ~~through a competitive bid process from one or more public or~~  
33 ~~private laboratories that meet the department's requirements for~~  
34 ~~testing, quality assurance, and reporting. If the department~~  
35 ~~determines that contracting for these services is more cost~~  
36 ~~effective, and meets the other requirements of this chapter, than~~  
37 ~~purchasing the tandem mass spectrometry equipment themselves,~~  
38 ~~the department shall contract with one or more public or private~~  
39 ~~laboratories.~~

~~(2) The prenatal screening fee increase for expanding prenatal screening to include inhibin and first trimester screening is forty dollars (\$40).~~

~~(e) (1) The department shall report to the Legislature regarding the progress of the program on or before July 1, 2006. The report shall include the costs for screening, followup, and treatment as compared to costs and morbidity averted for each condition tested for in the program.~~

~~(2) The department shall report to the Legislature regarding the progress of the program with regard to implementing prenatal screening for inhibin and first trimester screening, required pursuant to subdivision (b) on or before July 1, 2007. The report shall include the costs for screening, followup, and treatment as compared to costs and morbidity averted by this testing under the program.~~

~~SEC. 5.~~

*SEC. 4.* Section 125002 is added to the Health and Safety Code, to read:

125002. (a) In order to align closely related programs and in order to facilitate research into the causes of, and treatment for, birth defects, the Birth Defects Monitoring Program provided for pursuant to Chapter 1 (commencing with Section 103825) of Part 2 of Division 102 shall become part of the Maternal, Child, and Adolescent Health program provided for in Article 1 (commencing with Section 123225) of Chapter 1 of Part 2 of Division 106.

(b) It is the intent of the Legislature that pregnancy blood samples, taken for prenatal screening, shall be stored and used only for the following purposes:

(1) Research to identify risk factors for children's and women's diseases.

(2) Research to develop and evaluate screening tests.

(3) Research to develop and evaluate prevention strategies.

(4) Research to develop and evaluate treatments.

(c) Before any pregnancy blood samples are released for research purposes, all of the following conditions must be met:

(1) Individual consent at the time the sample is drawn to allow confidential use of the sample for research purposes by the department or the department's approved researchers.

1 (2) Protocol review for scientific merit by the department or  
2 another entity authorized by the department.

3 (3) Protocol review by the State Committee for the Protection  
4 of Human Subjects.

5 (d) When pregnancy blood samples are stored, analyzed or  
6 otherwise shared for research purposes with nondepartment staff,  
7 no information may be released identifying the person from  
8 whom the samples were obtained.

9 (e) Since the pregnancy blood samples described in this  
10 section will be stored by the California Birth Defects Monitoring  
11 Program or another entity authorized by the State Department of  
12 Health Services, Section 103850, pertaining to confidentiality of  
13 information, is applicable.

14 *SEC. 5. Section 125055 of the Health and Safety Code is*  
15 *amended to read:*

16 125055. The department shall:

17 (a) Establish criteria for eligibility for the prenatal testing  
18 program. Eligibility shall include definition of conditions and  
19 circumstances that result in a high risk of a detectable genetic  
20 disorder or birth defect.

21 (b) Develop an education program designed to educate  
22 physicians and surgeons and the public concerning the uses of  
23 prenatal testing and the availability of the program.

24 (c) Ensure that genetic counseling be given in conjunction  
25 with prenatal testing at the approved prenatal diagnosis centers.

26 (d) Designate sufficient prenatal diagnosis centers to meet the  
27 need for these services. Prenatal diagnosis centers shall have  
28 equipment and staff trained and capable of providing genetic  
29 counseling and performing prenatal diagnostic procedures and  
30 tests, including the interpretation of the results of the procedures  
31 and tests.

32 (e) Administer a program of subsidy grants for approved  
33 nonprofit prenatal diagnosis centers. The subsidy grants shall be  
34 awarded based on the reported number of low-income women  
35 referred to the center, the number of prenatal diagnoses  
36 performed in the previous year at that center, and the estimated  
37 size of unmet need for prenatal diagnostic procedures and tests in  
38 its service area. This subsidy shall be in addition to fees collected  
39 under other state programs.

(f) Establish any rules, regulations, and standards for prenatal diagnostic testing and the allocation of subsidies as the director deems necessary to promote and protect the public health and safety and to implement the Hereditary Disorders Act (Section 27).

(g) (1) *The department shall expand prenatal screening to include all tests that meet or exceed the current standard of care as recommended by nationally recognized medical or genetic organizations, including, but not limited to, inhibin.*

(2) *The prenatal screening fee increase for expanding prenatal screening to include those tests described in paragraph (1) is forty dollars (\$40).*

(3) *The department shall report to the Legislature regarding the progress of the program with regard to implementing prenatal screening for those tests described in paragraph (1) on or before July 1, 2007. The report shall include the costs of screening, followup, and treatment as compared to costs and morbidity averted by this testing under the program.*

(4) (A) *The expenditure of funds from the Genetic Disease Testing Fund for the expansion of the Genetic Disease Branch Screening Information System to include the expansion of prenatal screenings, pursuant to paragraph (1), may be implemented through the amendment of the Genetic Disease Branch Screening Information System contracts, and shall not be subject to Chapter 2 (commencing with Section 10290) or Chapter 3 (commencing with Section 12100) of Part 2 of Division 2 of the Public Contract Code, Article 4 (commencing with Section 19130) of Chapter 5 of Part 2 of Division 5 of Title 2 of the Government Code, or Sections 4800 to 5180, inclusive, of the State Administrative Manual as they relate to approval of information technology projects or approval of increases in the duration or costs of information technology projects. This paragraph shall apply to the design, development, and implementation of the expansion, and to the maintenance and operation of the Genetic Disease Branch Screening Information System, including change requests, once the expansion is implemented.*

(B) (i) *The department may adopt emergency regulations to implement and make specific the amendments to this section made during the 2006 portion of the 2005-06 Regular Session in*



1 accordance with Chapter 3.5 (commencing with Section 11340)  
2 of Part 1 of Division 3 of Title 2 of the Government Code. For  
3 the purposes of the Administrative Procedure Act, the adoption  
4 of regulations shall be deemed an emergency and necessary for  
5 the immediate preservation of the public peace, health and  
6 safety, or general welfare. Notwithstanding Chapter 3.5  
7 (commencing with Section 11340) of Part 1 of Division 3 of Title  
8 2 of the Government Code, these emergency regulations shall not  
9 be subject to the review and approval of the Office of  
10 Administrative Law. Notwithstanding Section 11346.1 and  
11 Section 11349.6 of the Government Code, the department shall  
12 submit these regulations directly to the Secretary of State for  
13 filing. The regulations shall become effective immediately upon  
14 filing by the Secretary of State. Regulations shall be subject to  
15 public hearing within 120 days of filing with the Secretary of  
16 State and shall comply with Sections 11346.8 and 11346.9 of the  
17 Government Code or shall be repealed.

18 (ii) The Office of Administrative Law shall provide for the  
19 printing and publication of these regulations in the California  
20 Code of Regulations. Notwithstanding Chapter 3.5 (commencing  
21 with Section 11340) of Part 1 of Division 3 of Title 2 of the  
22 Government Code, the regulations adopted pursuant to this  
23 chapter shall not be repealed by the Office of Administrative Law  
24 and shall remain in effect until revised or repealed by the  
25 department.

26 SEC. 6. No reimbursement is required by this act pursuant to  
27 Section 6 of Article XIII B of the California Constitution because  
28 the only costs that may be incurred by a local agency or school  
29 district will be incurred because this act creates a new crime or  
30 infraction, eliminates a crime or infraction, or changes the  
31 penalty for a crime or infraction, within the meaning of Section  
32 17556 of the Government Code, or changes the definition of a  
33 crime within the meaning of Section 6 of Article XIII B of the  
34 California Constitution.